

Amendment and Response

Page 3 of 7

Serial No.: 09/453,726

Confirmation No.: 2987

Filed: 2 December 1999

For: HYDROGEN PEROXIDE INDICATOR AND METHOD

Remarks

The Office Action mailed 25 September 2002 has been received and reviewed. Claims 1, 10, and 13 having been amended, the pending claims are claims 1-22.

Claims 1 and 10 have been amended to recite an indicator composition wherein the indicator composition does not include a halogen source. Applicant respectfully asserts that by reciting an indicator composition that does not include a halogen source, (e.g., by excluding the prior art), Applicant is not claiming new matter. Application of Johnson, 55 F.2d 1008, 1019 (1977) (Appendix B).

Claim 13 has been amended merely to correct a typographical error.

Reconsideration and withdrawal of the rejections in view of the above amendments and the following comments are respectfully requested.

The 35 U.S.C. §102 Rejection

The Examiner rejected claims 1-3, 5-6, 9-13, 15-16, and 19-22 under 35 U.S.C. §102(e) as being anticipated by Ignacio et al. (U.S. Patent No. 6,287,518). Applicant respectfully traverses this rejection.

The present claims recite an indicator composition wherein the indicator composition does not include a halogen source. The indicator composition of the present invention includes at least one component that is transformed (typically, chemically transformed) in the presence of vaporous hydrogen peroxide such that the color of the composition changes (specification, page 3, lines 23-26).

Ignacio et al., on the other hand, disclose a monitor composition that contains a dye and a halogen source, and a binder resin (Ignacio et al., column 3, lines 8-9). According to the disclosure of Ignacio et al., the dye is susceptible to halogenation in the presence of a halogen source and a peracid and changes color as a result of the halogenation (Ignacio et al., column 3, lines 10-12).

Amendment and Response

Serial No.: 09/453,726

Confirmation No.: 2987

Filed: 2 December 1999

For: HYDROGEN PEROXIDE INDICATOR AND METHOD

Page 4 of 7

As Applicant's claims recite an indicator composition that does not require a halogen source to provide a change in color in the presence of a sterilant, such as hydrogen peroxide, Applicant respectfully asserts that Ignacio et al. teach away from Applicant's claims.

Reconsideration and withdrawal of the rejection is respectfully requested.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 4 and 14 under 35 U.S.C. §103(a) as being unpatentable over Ignacio et al. (U.S. Patent No. 6,287,518) in view of Malchesky et al. (U.S. Patent No. 5,518,927).

The Examiner rejected claims 7 and 17 under 35 U.S.C. §103(a) as being unpatentable over Ignacio et al. (U.S. Patent No. 6,287,518) in view of Bealing et al. (U.S. Patent No. 5,990,199).

The Examiner rejected claims 8 and 18 under 35 U.S.C. §103(a) as being unpatentable over Ignacio et al. (U.S. Patent No. 6,287,518) in view of Bealing et al. (U.S. Patent No. 5,990,199) and further in view of Barrett (U.S. Patent No. 5,955,025).

Applicant respectfully traverses these rejections.

Applicant's claims include indicator compositions that may include Methylene violet (Color Index number (C.I.) 52041). Applicant respectfully submits that safranin, disclosed in Malchesky et al., is not synonymous with methylene violet. Safranin is a diazine dye that is synonymous with methylene violet RR (C.I. 50205, see Appendix C, H.J. Conn's Biological Stains, pages 382-384). Methylene violet RR (C.I. 50205) is not recited in Applicant's claims. Applicant's claims include Methylene violet (C.I. 52041), which is a thiazine dye and is structurally different from safranin (see Appendix D, H.J. Conn's Biological Stains, pages 429-430).

Applicant respectfully asserts, therefore, that the combination of Ignacio et al. with Malchesky et al. does not provide Applicant's claimed invention.

Drawn rather without halogen
no color indicator number in table how would one know with so many methylene violets that applicant intended CI 52041?

Amendment and Response

Serial No.: 09/453,726

Confirmation No.: 2987

Filed: 2 December 1999

For: HYDROGEN PEROXIDE INDICATOR AND METHOD

Page 5 of 7

Bealing et al. discloses indicators intended for use in sterilization processes that include not only hydrogen peroxide, but also sterilization processes under the conditions of heat, pressure, humidity, radiation, ethylene oxide, and combinations of these conditions (Bealing et al., column 5, lines 36-46). While Bealing et al. disclose the use of Janus green B colorant in their indicator compositions, it is a reactive dye that provides to the indicators of Bealing et al. a visible color change (Bealing et al., column 6, lines 10-27). ✓

added based on Ignacio et al. teaching of one that doesn't change color.

Claims 7 and 17 of the present invention recite the use of Janus green B as a colorant that does not change color upon contact with hydrogen peroxide. Applicant, therefore, asserts that not only does the disclosure of Janus green B in Bealing et al. in combination with Ignacio et al. not provide that which is missing from Ignacio et al., the disclosure of Bealing et al. teaches away from Applicant's claims.

Furthermore, Applicant submits that one of skill in the art would not be motivated to combine the teachings of Ignacio et al., with the teachings of Bealing et al. Applicant submits that one cannot simply substitute a colorant disclosed in Bealing et al. into the disclosure of Ignacio et al. and reasonably expect to successfully provide a sterilization indicator. Bealing et al. do not teach or suggest the use of a halogen source in their indicator compositions. There is no teaching or suggestion that Janus green B would be halogenated according to the disclosure of Ignacio et al. Therefore, one of skill would neither be motivated to combine the teachings of Ignacio et al. with those of Bealing et al., nor reasonably expect such combination to successfully provide a sterilization indicator composition according to the present claims. ✕

✕ Likewise, Barrett does not add that which is missing from Ignacio et al. or Bealing et al. As indicated above, Ignacio et al. disclose an indicator composition including a halogen source, while the present claims do not include a halogen source. Furthermore, Bealing et al. do not disclose Alkali blue 6B (acid blue 119). The Acid blue dyes disclosed in Bealing et al. are Acid blue #7 and Acid blue #20 (Bealing et al., column 6, lines 35-39). Applicant, therefore, respectfully asserts that as Ignacio et al. teach away from Applicant's claims, and Bealing et al.

Bealing used for Quinacridone red not Janus Green B

Amendment and Response

Page 6 of 7

Serial No.: 09/453,726

Confirmation No.: 2987

Filed: 2 December 1999

For: HYDROGEN PEROXIDE INDICATOR AND METHOD

do not disclose Alkali blue 6B (acid blue 119), the combination of the teachings of Ignacio et al., Bealing et al. and Barrett fail to provide Applicant's invention as recited in claims 8 and 18.

The Quinacridone red 19 of the present claims is a member of the Quinacridone chemical family and is available under the trade name Sunfast Red 19 (specification, page 23, Table 4; see Appendix E, Technical Data Sheet and Material Safety Data Sheet for SUNFAST Red 19, Sun Chemical Corporation), described as a high performance Quinacridone pigment.

Applicant respectfully asserts that Ignacio et al. teach away from Applicant's claimed invention. Furthermore, neither Ignacio et al. in combination with Malchesky et al., Ignacio et al. in combination with Bealing et al., nor Ignacio et al. in combination with Bealing et al. and Barrett provide Applicant's claimed invention. Reconsideration and withdrawal of the rejections are, therefore, respectfully requested.

Summary

It is respectfully submitted that the pending claims 1-22 are in condition for allowance and notification to that effect is respectfully requested.

Amendment and Response

Page 7 of 7

Serial No.: 09/453,726

Confirmation No.: 2987

Filed: 2 December 1999

For: HYDROGEN PEROXIDE INDICATOR AND METHOD

The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for

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PATENT TRADEMARK OFFICE

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26 December 2002

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on this 26th day of December, 2002, at 6:05 pm (Central Time).

By:

Name:

KATHLEEN L. FRANKLIN

**APPENDIX A - SPECIFICATION/CLAIM AMENDMENTS
INCLUDING NOTATIONS TO INDICATE CHANGES MADE**

Serial No.: 09/453,726

Docket No.: 52951US002 (formerly 52951USA7A)

Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted. Additionally, all amendments have been shaded.

In the Claims

For convenience, all pending claims are shown below.

1. (AMENDED) A hydrogen peroxide sterilization indicator comprising a substrate and an indicator composition disposed thereon, wherein the indicator composition comprises at least one colorant selected from the group consisting of Malachite green oxalate, Crystal violet, Methyl violet 2B, Ethyl violet, New fuchsin, Victoria blue B, Victoria pure blue BO, Toluidine blue O, Luxol brilliant green BL, Disperse blue 1, Brilliant blue R, Victoria blue R, Quinea green B, Thionine, Meldolas blue, Methylene green, Lissamine green B, Alkali blue 6B, Brilliant green, Spirit soluble HLK BASF, Victoria green S extra, Acid violet 17, Eriochrome black T, Eriochrome blue black B, D & C green no. 2, Spirit soluble fast RR, Spirit soluble fast red 3B, D & C red no. 22, Nitro red, Congo red, Brilliant cresyl blue ALD, Arsenazo 1, Basic red 29, Bismarck brown R, Methylene violet, Methylene violet 3RAX, Mordant brown 1, Reactive black 5, Mordant brown 48, Acid brown AX987, Acid violet AX990, Basic red 15, Mordant red 19, Bromopyrogallol red, and combinations thereof;

wherein the indicator composition does not include a halogen source.

2. The hydrogen peroxide sterilization indicator of claim 1, wherein the colorant is selected from the group consisting of Malachite green oxalate, Methyl violet 2B, New fuchsin, Toluidine blue O, Luxol brilliant green BL, Quinea green B, Thionine, Meldolas blue, Lissamine green B, Alkali blue 6B, Brilliant green, Victoria green S extra, Eriochrome blue black B, Congo red, Bismarck brown R, Methylene violet, Methylene violet 3RAX, Bromopyrogallol red, and combinations thereof.

Amendment and Response - - Appendix A

Page A-2

Serial No.: 09/453,726

Confirmation No.: 2987

Filed: 2 December 1999

For: HYDROGEN PEROXIDE INDICATOR AND METHOD

3. The hydrogen peroxide sterilization indicator of claim 2, wherein the colorant is selected from the group consisting of Malachite green oxalate, Methyl violet 2B, New fuchsin, Quinea green B, Thionine, Meldolas blue, Lissamine green B, Alkali blue 6B, Congo red, Eriochrome blue black B, Bismarck brown R, Methylene violet 3RAX, and combinations thereof.
4. The hydrogen peroxide sterilization indicator of claim 2, wherein the colorant is selected from the group consisting of Toluidine blue O, Luxol brilliant green BL Victoria green S extra, Methylene violet, Bromopyrogallol red, Brilliant green, and combinations thereof.
5. The hydrogen peroxide sterilization indicator of claim 1, wherein the colorant is selected from the group consisting of Ethyl violet, New fuchsin, Toluidine blue O, Luxol brilliant green BL, Disperse blue 1, Brilliant blue R, Quinea green B, Thionine, Meldolas blue, Methylene green, Lissamine green B, Alkali blue 6B, Brilliant green, Spirit soluble HLK BASF, Victoria green S extra, Acid violet 17, Eriochrome black T, Eriochrome blue black B, D & C green no. 2, Spirit soluble fast RR, Spirit soluble fast red 3B, D & C red no. 22, Nitro red, Congo red, Brilliant cresyl blue ALD, Arsenazo 1, Basic red 29, Bismarck brown R, Methylene violet, Methylene violet 3RAX, Mordant brown 1, Reactive black 5, Mordant brown 48, Acid brown AX987, Acid violet AX990, Mordant red 19, Bromopyrogallol red, and combinations thereof.
6. The hydrogen peroxide sterilization indicator of claim 1, wherein the indicator composition further comprises at least one colorant that does not change color upon contact with hydrogen peroxide vapor.
7. The hydrogen peroxide sterilization indicator of claim 6, wherein the colorant that does not change color upon contact with hydrogen peroxide vapor is selected from the group consisting Quinacridone red 19, Auramine O, Brilliant blue G, Acid black 24, Patent blue violet,

Amendment and Response -- Appendix A

Page A-3

Serial No.: 09/453,726

Confirmation No.: 2987

Filed: 2 December 1999

For: HYDROGEN PEROXIDE INDICATOR AND METHOD

Disperse red 13, Sudan black B, Janus green B, Acridine orange base, Fast green FCF, Patent blue VF, Acid red 97, Sulforhodamine B, Xylenol orange sodium salt, Azure B, Spirit soluble fast yellow G, Keystone soap fluoro green, Calco oil blue N, Oil blue A, Calco oil green, D & C red no. 33, D & C green no.5, Bordeaux R, Xylenol cyanole FF, Crystal scarlet, Basic blue 41, Evans blue, Chicago sky blue 6B, Acid blue 113, Acid blue 120, Acid red 88, Acid red 151, Acid violet 5, Disperse red 1, Direct red 81, Disperse red 19, Sudan red 7B, Basic red 73, Acid green AX986, and combinations thereof.

8. The hydrogen peroxide sterilization indicator of claim 7, wherein the indicator composition comprises Alkali blue 6B and Quinacridone red 19.

9. The hydrogen peroxide sterilization indicator of claim 1, wherein the substrate is a polyester film.

10. (AMENDED) A hydrogen peroxide sterilization indicator comprising a substrate and an indicator composition disposed thereon, wherein the indicator composition comprises a binder, at least one colorant selected from the group consisting of Malachite green oxalate, Crystal violet, Methyl violet 2B, Ethyl violet, New fuchsin, Victoria blue B, Victoria pure blue BO, Toluidine blue O, Luxol brilliant green BL, Disperse blue 1, Brilliant blue R, Victoria blue R, Quinea green B, Thionine, Meldolas blue, Methylene green, Lissamine green B, Alkali blue 6B, Brilliant green, Spirit soluble HLK BASF, Victoria green S extra, Acid violet 17, Eriochrome black T, Eriochrome blue black B, D & C green no. 2, Spirit soluble fast RR, Spirit soluble fast red 3B, D & C red no. 22, Nitro red, Congo red, Brilliant cresyl blue ALD, Arsenazo 1, Basic red 29, Bismarck brown R, Methylene violet, Methylene violet 3RAX, Mordant brown 1, Reactive black 5, Mordant brown 48, Acid brown AX987, Acid violet AX990, Basic red 15, Mordant red 19, Bromopyrogallol red, and combinations thereof, and at least one colorant that does not change color upon contact with hydrogen peroxide vapor;

Amendment and Response -- Appendix A

Page A-4

Serial No.: 09/453,726

Confirmation No.: 2987

Filed: 2 December 1999

For: HYDROGEN PEROXIDE INDICATOR AND METHOD

wherein the indicator composition does not include a halogen source.

11. A method of monitoring a hydrogen peroxide sterilization process, the method comprising exposing an article to be sterilized and the hydrogen peroxide sterilization indicator of claim 1 to hydrogen peroxide vapor.
12. The method of claim 11, wherein the colorant is selected from the group consisting of Malachite green oxalate, Methyl violet 2B, New fuchsin, Toluidine blue O, Luxol brilliant green BL, Quinea green B, Thionine, Meldolas blue, Lissamine green B, Alkali blue 6B, Brilliant green, Victoria green S extra, Eriochrome blue black B, Congo red, Bismarck brown R, Methylene violet, Methylene violet 3RAX, Bromopyrogallol red, and combinations thereof.
13. (AMENDED) The method of claim 12, wherein the colorant is selected from the group consisting of Malachite green oxalate, Methyl violet 2B, New fuchsin, [,] Quinea green B, Thionine, Meldolas blue, Lissamine green B, Alkali blue 6B, Congo red, Eriochrome blue black B, Bismarck brown R, Methylene violet 3RAX, and combinations thereof.
14. The method of claim 12, wherein the colorant is selected from the group consisting of Toluidine blue O, Luxol brilliant green BL, Victoria green S extra, Methylene violet, Bromopyrogallol red, Brilliant green, and combinations thereof.
15. The method of claim 11, wherein the colorant is selected from the group consisting of Ethyl violet, New fuchsin, Toluidine blue O, Luxol brilliant green BL, Disperse blue 1, Brilliant blue R, Quinea green B, Thionine, Meldolas blue, Methylene green, Lissamine green B, Alkali blue 6B, Brilliant green, Spirit soluble HLK BASF, Victoria green S extra, Acid violet 17, Eriochrome black T, Eriochrome blue black B, D & C green no. 2, Spirit soluble fast RR, Spirit soluble fast red 3B, D & C red no. 22, Nitro red, Congo red, Brilliant cresyl blue ALD,

Amendment and Response -- Appendix A

Page A-5

Serial No.: 09/453,726

Confirmation No.: 2987

Filed: 2 December 1999

For: HYDROGEN PEROXIDE INDICATOR AND METHOD

Arsenazo 1, Basic red 29, Bismarck brown R, Methylene violet, Methylene violet 3RAX, Mordant brown 1, Reactive black 5, Mordant brown 48, Acid brown AX987, Acid violet AX990, Mordant red 19, Bromopyrogallol red, and combinations thereof.

16. The method of claim 11, wherein the indicator composition further comprises at least one colorant that does not change upon contact with hydrogen peroxide vapor.

17. The method of claim 16, wherein the colorant that does not change color upon contact with hydrogen peroxide vapor is selected from the group consisting of Quinacridone red 19, Auramine O, Brilliant blue G, Acid black 24, Patent blue violet, Disperse red 13, Sudan black B, Janus green B, Acridine orange base, Fast green FCF, Patent blue VF, Acid red 97, Sulforhodamine B, Xylenol orange sodium salt, Azure B, Spirit soluble fast yellow G, Keystone soap fluoro green, Calco oil blue N, Oil blue A, Calco oil green, D & C red no. 33, D & C green no.5, Bordeaux R, Xylenol cyanole FF, Crystal scarlet, Basic blue 41, Evans blue, Chicago sky blue 6B, Acid blue 113, Acid blue 120, Acid red 88, Acid red 151, Acid violet 5, Disperse red 1, Direct red 81, Disperse red 19, Sudan red 7B, Basic red 073, Acid green AX986, and combinations thereof.

18. The method of claim 17, wherein the indicator composition comprises Alkali blue 6B and Quinacridone red 19.

19. The method of claim 11, wherein the substrate is a polyester film.

20. The method of claim 11, wherein the binder is shellac.

21. The hydrogen peroxide sterilization indicator of claim 1, wherein the

Amendment and Response -- Appendix A

Page A-6

Serial No.: 09/453,726

Confirmation No.: 2987

Filed: 2 December 1999

For: HYDROGEN PEROXIDE INDICATOR AND METHOD

colorant is selected from the group consisting of of Malachite green oxalate, Methyl violet 2B, Ethyl violet, New fuchsin, Victoria blue B, Victoria pure blue BO, Toluidine blue O, Luxol brilliant green BL, Disperse blue 1, Brilliant blue R, Victoria blue R, Quinea green B, Thionine, Meldolas blue, Methylene green, Lissamine green B, Alkali blue 6B, Spirit soluble HLK BASF, Victoria green S extra, Acid violet 17, Eriochrome black T, Eriochrome blue black B, D & C green no. 2, Spirit soluble fast RR, Spirit soluble fast red 3B, D & C red no. 22, Nitro red, Congo red, Brilliant cresyl blue ALD, Arsenazo 1, Basic red 29, Bismarck brown R, Methylene violet, Methylene violet 3RAX, Mordant brown 1, Reactive black 5, Mordant brown 48, Acid brown AX987, Acid violet AX990, Basic red 15, Mordant red 19, Bromopyrogallol red, and combinations thereof.

22. The method of claim 11, wherein the article to be sterilized and the hydrogen peroxide sterilization indicator are exposed to hydrogen peroxide vapor at a temperature of about 45°C to about 50°C and a pressure of about 8×10^2 Pascals to about 13.3×10^2 Pascals.